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John Vanden Hock

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EXAMINER

KRAMER, NICOLE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/663,623

Applicant(s)

HOEK ET AL.

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-24 is/are pending in the application.  
4a) Of the above claim(s) 19-24 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 3-8 is/are rejected.  
7) ☒ Claim(s) 9-18 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/21/2006.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,973,300 ("Wright").

Wright discloses a method for applying a cardiac support device to a heart of a mammal (Wright is directed to a cardiac sling for supporting the heart during surgery), the method comprising: (a) surgically accessing a heart (the heart is necessarily surgically accessed in order to position the sling under the heart); (b) providing a cardiac support device including a jacket (Examiner considers sling 3 of Wright to be a jacket since it encloses the heart); and (c) positioning the jacket around at least a portion of the heart by applying a pulling force to the jacket (the sling is positioned around the heart by pulling the sling's tapes 8 and 9; see col. 3, line 58 - col. 4, line 6).

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In order to pull the tapes 8 and 9 using curved forceps as shown in Figures 5 and 6, the pulling force is necessarily from a position superior to the heart. In further placing the sling around the heart as shown in Figures 7 and 8, Wright explicitly discloses that the sling is pulled "upwards and towards the surgeon, as depicted by the arrows in Figs. 7 and 8" at col. 4, lines 4-6. In order to pull the sling upwards and towards the surgeon, the pulling force is necessarily from a position superior to the heart).

With respect to claim 3, the step of positioning includes pulling in a first direction a first portion of the jacket onto the heart (one tape 8/9 is pulled in a first direction as shown in Figure 5), and pulling in a second direction a second portion of the jacket onto the heart (the other tape 8/9 is pulled in a second direction as shown in Figure 6).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,702,343 ("Alferness") in view of U.S. Patent No. 5,735,290 ("Serman et al.") or U.S. Patent No. 4,973,300 ("Wright").

Alferness discloses a method for applying a cardiac support device to a heart of a mammal (Alferness is directed to a cardiac reinforcement device or CRD), the method comprising: (a) surgically accessing a heart (the CRD can be applied to the epicardium

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of a heart through a thoracotomy or through a minimally invasive procedure through a thorascopic incision; see col. 5, line 54 - col. 6, line 10; see also Fig. 7 and associated text at col. 7, lines 25-33 for a description of a placement tool 60 for placing the CRD jacket around the epicardium of the heart); (b) providing a cardiac support device including a jacket (CRD may be jacket 15; see Fig. 3 and associated text); and (c) positioning the jacket around at least a portion of the heart by applying a pulling force to the jacket (the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23; see col. 4, lines 52-65 and col. 6, lines 29-39. In order to move the opposing edge of the slot closer together, a pulling force is necessarily applied to fasteners 22 and 23). Alferness describes that after the CRD is in position over the epicardial surface, a second incision is made to provide access for suitable surgical instruments to secure or adjust the size of the CRD (see col. 6, lines 8-10).

Alferness fails to specifically disclose that the second incision is made from a position superior to the heart and/or delivery device. However, it is known in the art to access the heart from a position superior to the heart (for example, see U.S. Patent No. 5,735,290 to Sterman et al. which discloses that a grasper or other tool for applying tension may be advanced through a trocar 10 from a position superior to the heart; see Figure 4 and col. 8, lines 37-54. See also, U.S. Patent No. 4,973,300 to Wright which teaches positioning a cardiac sling over a heart by applying a pulling force to the sling from a position superior to the heart using curved forceps; see Figures 5-6 and associated text at col. 3, line 58 - col. 4, line 6). Since the size of jacket 15 of Alferness is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and

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23, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention for the second incision for providing access for suitable surgical instruments to secure or adjust the CRD to be from a position superior to the heart and/or delivery device, because the pulling forces to secure and/or adjust the cone-shaped CRD are necessarily upwards (in order to secure the broader base of the jacket around the base portion of the heart, and secure the apex of the jacket around the apex of the heart as described at col. 4, line 11-22)) and towards the opposing side of the slot (in order to selectively adjust the size of the jacket as previously described) in order to securely fit the CRD jacket over the surface of the heart and thus may be most effectively performed from an incision location superior to the heart and delivery device incision.

With respect to claim 3, as described above, Alferness discloses that the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23; see col. 4, lines 52-65 and col. 6, lines 29-39. In order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to adjust the jacket around the heart.

With respect to claims 6 and 8, as described above, in order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to

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adjust the jacket around the heart. Further, Alferness discloses suitable surgical instruments are utilized to secure or adjust the size of the CRD (see col. 6, lines 8-10). In order to utilize a surgical instrument to manipulate fasteners 22 and 23, the surgical instrument must grasp the fasteners, which are strands secured to the jacket.

With respect to claim 7, Alferness fails to disclose removing the tool from the thorax and surgically inserting the tool into another location in the thorax in a position superior to the delivery device in order to use the tool to pull in a second direction. As previously noted, in order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to adjust the jacket around the heart. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to make another incision for applying the second pulling force because the second pulling force is necessarily in the opposite direction as the first pulling force (that is, towards the opposite lateral edge of the slot) and thus may be more effectively performed from a different incision location.

***Allowable Subject Matter***

6. Claims 9 (and 10-18 depending therefrom) are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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7. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest a cardiac jacket comprising (A) a first anterior strand secured to the base edge adjacent to first lateral edge; (B) a second anterior strand secured to the base edge adjacent to the second lateral edge; (C) a first posterior strand secured to the base edge and positioned closer to the first anterior strand than to the second anterior strand; and (D) a second posterior strand secured to the base edge and positioned closer to the second anterior strand than to the first anterior strand, wherein the step of positioning the jacket around at least a portion of the heart includes pulling each of the first anterior, second anterior, first posterior, and second posterior strands to pull the jacket around the heart.

### ***Response to Arguments***

8. Applicant's arguments filed 8/3/06 have been fully considered but they are not persuasive. In particular, Applicant argues that the procedures of Alferness take place from locations generally below or on the side of the heart, and there is no suggestion that the pulling forces (to pull the lateral edges of the cardiac jacket together) are applied from a location superior to the heart (see page 11 of Response filed 8/3/06). When discussing that a second incision is made to provide access for suitable surgical instruments to secure or adjust the size of the CRD (see col. 6, lines 8-10), Alferness makes no suggestion whatsoever of the location of the second incision. However, as explained in the rejection above, it is known in the art to access the heart from a position superior to the heart (for example, see U.S. Patent No. 5,735,290 to Sterman et



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al. which discloses that a grasper or other tool for applying tension may be advanced through a trocar 10 from a position superior to the heart; see Figure 4 and col. 8, lines 37-54. See also, U.S. Patent No. 4,973,300 to Wright which teaches positioning a cardiac sling over a heart by applying a pulling force to the sling from a position superior to the heart using curved forceps; see Figures 5-6 and associated text at col. 3, line 58 - col. 4, line 6). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to modify the method disclosed in Alferness is in the knowledge generally available to one of ordinary skill in the art. Since the size of jacket 15 of Alferness is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention for the second incision for providing access for suitable surgical instruments to secure or adjust the CRD to be from a position superior to the heart and/or delivery device, because the pulling forces to secure and/or adjust the cone-shaped CRD are necessarily upwards (in order to secure the broader base of the jacket around the base portion of the heart, and secure the apex of the jacket around the apex of the heart as described at col. 4, line 11-22)) and towards the opposing side of the slot (in order to selectively adjust the size of the jacket as previously described) in order to securely fit the CRD jacket over the

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surface of the heart and thus may be most effectively performed from an incision location superior to the heart and delivery device incision.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK  
NRK

9/26/06

  
George Manuel  
Primary Examiner